PUBLISHED

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

No. 13-2146

MICHELLE NEMPHOS, as Legal Guardian for C.G.N., a Minor under the age of Eighteen,

Plaintiff - Appellant,

v.

NESTLE WATERS NORTH AMERICA, INC.; NESTLE USA, INC.; THE DANNON COMPANY, INC.; GERBER PRODUCTS COMPANY,

Defendants - Appellees.

Appeal from the United States District Court for the District of Maryland, at Baltimore. George L. Russell, III, District Judge. (1:12-cv-02718-GLR)

Argued: October 30, 2014 Decided: January 8, 2015

Before WILKINSON, MOTZ, and FLOYD, Circuit Judges.

Affirmed by published opinion. Judge Wilkinson wrote the opinion, in which Judge Motz and Judge Floyd joined.

ARGUED: Leah Marie Nicholls, PUBLIC JUSTICE, P.C., Washington, D.C., for Appellant. Catherine Emily Stetson, HOGAN LOVELLS US LLP, Washington, D.C.; Peter Buscemi, MORGAN LEWIS & BOCKIUS LLP, Washington, D.C., for Appellees. **ON BRIEF:** Leslie A. Brueckner, PUBLIC JUSTICE, P.C., Oakland, California; Christopher T. Nidel, NIDEL LAW, PLLC, Washington, D.C.; Christopher T. Nace, PAULSON & NACE, Washington, D.C., for Appellant. Victoria J. Miller, Kristin M. Hadgis, MORGAN, LEWIS & BOCKIUS LLP, Philadelphia, Pennsylvania, for Appellee The

Dannon Company, Inc. Lauren S. Colton, Baltimore, Maryland, Michael L. Kidney, HOGAN LOVELLS US LLP, Washington, D.C., for Appellees Nestle USA, Inc., Nestle Waters North America, Inc., and Gerber Products Company.

WILKINSON, Circuit Judge:

Appellant Michelle Nemphos filed suit against the manufacturers of bottled water, infant formula, and baby food that her minor daughter had consumed before developing a condition known as dental fluorosis. Nemphos brought an array of tort and fraud claims under Maryland law against appellee manufacturers Nestlé Waters North America, Inc., Nestlé USA, Inc., The Dannon Company, Inc., and Gerber Products Company. The question in this appeal is whether federal law, which provides uniform labeling standards for the products at issue, preempts Nemphos's state-law claims. We hold that federal law preempts Nemphos's bottled water claims and that her complaint as to the infant formula and baby food products fails to satisfy the pleading requirements of Federal Rule of Civil Procedure 8(a)(2). We thus affirm the district court's dismissal of her action.

I.

Because the district court dismissed Nemphos's claims under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim, we review legal issues de novo and treat the facts alleged in the complaint as true. Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555-56 (2007); Neitzke v. Williams, 490 U.S. 319, 326-27 (1989).

A.

Nemphos alleges that her minor daughter, C.G.N., consumed appellees' products throughout her childhood. From her birth in 1997 until approximately her first birthday, C.G.N. was fed Nestlé's Carnation Good Start infant formula, in lieu of breastfeeding. From approximately four months to one year of age, C.G.N. ate Gerber baby foods almost exclusively, including Gerber apple juice that was often mixed into her water. From approximately six months to eight years of age, C.G.N. also habitually drank Nestlé's Poland Spring fluoridated bottled water and Dannon's Fluoride To Go bottled water.

According to Nemphos, C.G.N. developed dental fluorosis from consuming the appellee manufacturers' products. Although fluoridated drinking water can play a significant role in preventing tooth decay in children and adults, young children who consume too much fluoride may develop dental fluorosis -- a change in the appearance of tooth enamel. Nemphos's complaint does not specify the precise extent of C.G.N.'s fluoride-related injuries, but symptoms may range from specks and discoloration of teeth in mild cases to mottling and pitting in more severe ones.

Dental fluorosis results when young children ingest excessive fluoride over an extended period of time, while their adult teeth are still developing below the surface of their

gums. To address that risk, federal agencies such as the Food and Drug Administration ("FDA") issue recommendations and regulations for safe water fluoridation levels. The products at issue in this case are not alleged to have violated federal fluoride requirements.

B.

In September 2012, Nemphos filed a complaint on her daughter's behalf against the appellee manufacturers. Although all of Nemphos's claims were based on Maryland law, she brought suit in federal district court because the parties are citizens of different states. See 28 U.S.C. § 1332(a). The complaint alleged that the manufacturers had failed to warn about the risks of dental fluorosis for children who consume large amounts of fluoride, and that they had misleadingly marketed their fluoride-containing products as especially beneficial to children. Consequently, the complaint maintained, "C.G.N. has suffered, and continues to suffer from, physical and emotional damages related to her injuries from fluoride, which include, but are not limited to, dental fluorosis." J.A. 13. Nemphos's complaint asserted six causes of action under Maryland law: strict liability (Count I), negligence (Count II), breach of implied warranties (Count III), fraud (Count IV), negligent infliction of emotional distress (Count V), and violations of

the Maryland Consumer Protection Act, which prohibits unfair and deceptive trade practices (Count VI). In response, appellees filed motions to dismiss the complaint under Rule 12(b)(6), for failure to state a claim upon which relief can be granted.

The district court granted the motions and dismissed Nemphos's complaint with prejudice. The court concluded that federal law preempted Nemphos's state-law claims. The appellee manufacturers' products were already subject either to a federal "standard of identity" or to other federal labeling regulations. Granting the relief requested by Nemphos, the court found, would have required appellees' products to have fluoride levels below the FDA's established limits or to bear warnings not mandated by the FDA. In other words, Nemphos sought to impose a duty under Maryland law that was not identical to the existing federal requirements.[1] Nemphos now challenges the court's dismissal of her suit.[2]

[1] Although the underlying merits of Nemphos's state-law claims are not directly at issue in this appeal, as a substantive matter the district court's opinion left open only her tort claims invoking strict liability (Count I) and negligence (Count II). Prior to the court's decision, Nemphos had already conceded that Maryland law would not countenance an independent claim for negligent infliction of emotional distress (Count V). In its memorandum opinion, the court deemed all of Nemphos's claims preempted, but it nevertheless proceeded to find that her claims regarding breach of implied warranties (Count III), fraud (Count IV), and Maryland Consumer Protection Act violations (Count VI) all failed under Maryland law. The (Continued)

II.

Nemphos first argues that federal law does not preempt her state-law claims about Nestlé's and Dannon's bottled water products. Specifically, she alleges that Nestlé and Dannon failed to warn about the risks of dental fluorosis and engaged in misleading marketing. To assess the viability of Nemphos's bottled water claims, we first need to examine the federal statutory and regulatory framework, with particular attention to the relevant preemption structure. We will then consider her failure-to-warn and misleading-marketing claims.

A.

For more than a century, the FDA has been charged with protecting Americans against foods and drugs that are "misbranded" or "adulterated." See Federal Food, Drug, and Cosmetic Act ("FDCA"), ch. 675, 52 Stat. 1040 (1938); Pure Food Act, ch. 3915, 34 Stat. 768 (1906); see 21 U.S.C. § 331. Today, a core element of the FDA's mission is to "protect the public

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district court did not address the substance of Nemphos's strict liability and negligence claims, nor did it need to do so.

[2] Nemphos also seeks leave to amend her complaint on remand. Because we find her claims preempted, we likewise agree with the district court's denial of Nemphos's request on the ground that any amendment would be futile. See Fed. R. Civ. P. 15(a); Foman v. Davis, 371 U.S. 178, 182 (1962); Laber v. Harvey, 438 F.3d 404, 426 (4th Cir. 2006) (en banc).

health by ensuring that . . . foods are safe, wholesome, sanitary, and properly labeled." 21 U.S.C. § 393(b)(2)(A). The states have also played important roles in food and drug regulation since the time when they were only colonies. See Wallace F. Janssen, America's First Food and Drug Laws, 30 Food Drug Cosm. L.J. 665 (1975). Even as federal laws remain supreme, U.S. Const. art. VI, cl. 2, the United States has developed a dual system of food and drug regulation. A federal law may preempt state intervention in one aspect of a given food, for example, while allowing states to act on other aspects of the same food. Lofty questions about federal-state relations, however, are not urged upon us in this appeal, and our ruling does not disturb the balance that has been carefully struck over the years. This case turns on a relatively narrow issue of statutory interpretation.

The federal Nutrition Labeling and Education Act of 1990 ("NLEA"), Pub. L. No. 101-535, 104 Stat. 2353, secures the FDA's authority to oversee food labeling. In passing the NLEA, Congress underscored its intent "to clarify and to strengthen the Food and Drug Administration's legal authority to require nutrition labeling on foods, and to establish the circumstances under which claims may be made about nutrients in foods." H.R. Rep. No. 101-538, at 7 (1990), reprinted in 1990 U.S.C.C.A.N. 3336, 3337. The NLEA builds on the FDCA to develop a nationwide

system of uniform nutrition labeling for covered foods, in part by requiring meaningful disclosures about certain nutrients contained in those foods. Id.; see 21 U.S.C. §§ 343, 343-1.

The uniform labeling system instituted by the FDCA and fortified by the NLEA benefits both manufacturers and consumers of food products. See 21 U.S.C. § 341; POM Wonderful LLC v. Coca-Cola Co., 134 S. Ct. 2228, 2234, 2238-40 (2014); 62 Cases of Jam v. United States, 340 U.S. 593, 596 (1951); Fed. Sec. Adm'r v. Quaker Oats Co., 318 U.S. 218, 230-31 & n.7 (1943). Manufacturers can produce and market foods consistently and cost-effectively across the United States. Consumers gain a reliable and comprehensible means of ascertaining the nutritional content of the foods they buy, wherever they may live or travel in this country. Armed with such information, consumers can make well-informed decisions about the types and quantities of ingredients in their diets.

B.

A system engineered to ensure national uniformity must exclude some local disuniformities. While the NLEA provides a nationwide framework for certain types of food labeling, it likewise prohibits states from disrupting that arrangement with nonidentical requirements. The Act struck a necessary balance between the two fonts of regulatory authority -- between uniform

federal labeling standards and potentially more stringent laws in individual states. As the FDA has explained, "Congress decided that even though Federal requirements may preempt more restrictive State requirements in certain instances, the net benefits from national uniformity in these aspects of the food label outweigh the loss in consumer protection that may occur as a result." State Petitions Requesting Exemption from Federal Preemption, 58 Fed. Reg. 2462, 2462 (Jan. 6, 1993).

To maintain that balance, the NLEA includes a series of express preemption provisions. 21 U.S.C. § 343-1(a)(1)-(5). These provisions -- under the heading "National uniform nutrition labeling" -- forbid states from establishing any requirement that is "not identical to" the federal requirements in five areas of food labeling. Id. One of those areas, and the one at issue in Nemphos's bottled water claims, concerns the "standard of identity." Id. § 343-1(a)(1).

This preemption provision, subsection (a)(1), provides as follows:

> (a) Except as provided in subsection (b) of this section, no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce --
>
> > (1) any requirement for a food which is the subject of a standard of identity established under section 341 of this title that is not identical to such standard of identity or that is not identical to the requirement of section

> 343(g) of this title, except that this paragraph does not apply to a standard of identity of a State or political subdivision of a State for maple syrup that is of the type required by sections 341 and 343(g) of this title . . . .

Id.; see also NLEA § 6(c)(1), 104 Stat. at 2364, reprinted in 21 U.S.C. § 343-1, at 87 (specifying that the NLEA preempts state law only expressly). Several contextual points help to clarify this language. First, § 341 empowers the FDA to establish "a reasonable definition and standard of identity" for almost any food. Id. § 341. Second, § 343(g) deems a food product "misbranded" if it is represented as a particular food yet fails to conform to the standard of identity. Id. § 343(g). Third, subsection (a)(1) allows a conspicuous exception to preemption for but a single product: maple syrup. Id. § 343-1(a)(1). Last, § 343-1(b) enables the FDA, "[u]pon petition of a State or a political subdivision," to exempt certain state or local requirements that would otherwise be barred by subsection (a)(1) or the four other preemption provisions. Id. § 343-1(b).

Within this context, the force of subsection (a)(1) is apparent. First, the statute preempts "any" applicable state requirement, not just some of them. Id. § 343-1(a)(1). Second, the statute preempts any nonidentical state requirement for a "food" that is the subject of a federal standard of identity; that is, the preempted requirement may be any conflicting state-law obligation for that food. Id. Third and finally, subsection

(a)(1) uses the unequivocal phrase "not identical to" the standard of identity. Id. It does not say any state requirement merely "differing from," "conflicting with," "inconsistent with," or "dissimilar to" the federal requirement. Nor does the statute employ here the more limited phrase "in violation of" -- as it does regarding the petition process, later in the same section. Id. § 343-1(b). The four subsequent preemption provisions use the same "not identical to" phrasing toward other categories of labeling requirements. Id. § 343-1(a)(2)-(5). Put simply, then, we can understand subsection (a)(1) this way: for a food that is the subject of a federal standard of identity, this provision preempts any pertinent state requirement that is not identical to the federal requirement. Id. § 343-1(a)(1).

The NLEA does afford a specific exception to its preemption provisions -- for state-generated "safety" warnings. The preemption provisions in § 343-1 do not "apply to any requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food." NLEA § 6(c)(2), 104 Stat. at 2364, reprinted in 21 U.S.C. § 343-1, at 87. In the context of food additives, the FDA defines "safety" as entailing "a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use." 21 C.F.R. § 170.3(i). Establishing "complete certainty" of

"absolute harmlessness" is not required. Id. Although the NLEA's preemption provisions sweep broadly, state-law duties may be insulated from the Act's preemptive reach if they involve warnings about food "safety."

C.

A standard of identity specifies the defining characteristics of a given food. 21 U.S.C. § 341; see also id. § 343(g). To "promote honesty and fair dealing in the interest of consumers," the FDCA allows the FDA to "promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity," as well as standards of quality and fill. Id. § 341. This power to determine standards of identity -- in essence, to regulate the ingredients of a food and its representation in interstate commerce -- is "far-reaching." 62 Cases of Jam, 340 U.S. at 598.

The standard of identity is important to the FDA's capacity to regulate those characteristics of a food label that would enable a food to be marketed as such, and to ensure that certain foods accord with consumer expectations. Specifically, to be marketed in interstate commerce under a given name -- such as "bottled water" -- a food must conform to the standard of identity. See 21 U.S.C. §§ 331, 341, 343(g); 62 Cases of Jam,

340 U.S. at 598; see also 21 C.F.R. § 101.3. At the consumer level, a standard of identity warrants that individuals will encounter a label reflecting the food's actual contents -- that consumers "will get what they may reasonably expect to receive." Quaker Oats, 318 U.S. at 232. Significantly, the FDA may also distinguish "optional ingredients" that manufacturers can add to a food that is subject to a standard of identity. 21 U.S.C. §§ 341, 343(g). Any optional ingredients present must be "named on the label." Id. § 341; see id. § 343(g).

Although the details vary from food to food, fundamentally the standard of identity focuses on the contents of a food and the way those contents are represented to consumers. Under the NLEA's amendments, the FDA now establishes standards of identity through the agency's conventional rulemaking process. 21 U.S.C. § 371; 21 C.F.R. § 10.40; see James T. O'Reilly, 1 Food and Drug Administration § 10:29 & n.8 (3d ed. 2014). Standards of identity have been utilized to delineate the accepted composition of a food, to indicate permissible formulations or varieties of ingredients, to note optional or prohibited ingredients, to describe appropriate manufacturing processes, to detail methods of product analysis, to designate a commercial name, to set ingredient-related labeling requirements. See 21 C.F.R. pts. 130-169; see, e.g., id. § 131.110 (milk); id. § 131.200 (yogurt); id. § 137.105 (flour); id. § 139.110

(macaroni products); id. § 145.110 (canned applesauce); id. § 150.160 (fruit preserves and jams); id. § 155.190 (canned tomatoes); id. § 155.130 (canned corn); id. § 163.130 (milk chocolate); id. § 169.140 (mayonnaise). In addition to various descriptive provisions, a "label declaration" regarding a food's ingredients often appears in these regulations. See, e.g., id. §§ 131.110(f), 137.105(b)(1), 139.110(g), 145.110(a)(4), 150.160(e)(2), 155.190(a)(6), 155.130(a)(5), 163.130(d), 169.140(f).

The FDA regulates bottled water as a food, and the agency has developed a standard of identity for bottled water. 21 C.F.R. § 165.110; see also Beverages: Bottled Water, 60 Fed. Reg. 57,076, 57,076 (Nov. 13, 1995) (noting that the FDA had received some 430 responses to the proposed standard during the comment period). Under the FDA's standard of identity, "bottled water" is defined as "water that is intended for human consumption and that is sealed in bottles or other containers with no added ingredients except that it may optionally contain safe and suitable antimicrobial agents." Id. § 165.110(a)(1). The standard of identity also classifies fluoride as an optional ingredient in bottled water. Id. Manufacturers may add fluoride to bottled water within the limitations established in the FDA's "standard of quality" for bottled water, which sets microbiological, physical, chemical, and radiological

specifications. Id.; see id. § 165.110(b)(2)-(5) (standard of quality); id. § 165.110(b)(4)(ii) (fluoride levels). The specific concentration of fluoride permitted depends on what the retail location's average maximum daily air temperature is, whether the bottled water is packaged domestically or imported, and whether fluoride has been added. See id. § 165.110(b)(4)(ii)(A)-(D). If fluoride or any other optional ingredient has been added to the bottled water, the label must list each of the ingredients. Id. §§ 101.4(a)(1), 130.3(e), 165.110(a)(4).

Nemphos attempts to ascribe a very restrictive role to standards of identity, claiming flatly that "Federal Standards of Identity . . . Do Not Address Warnings." Appellant's Reply Br. at 12; see Appellant's Br. at 36. Aside from the incorrectness of this statement as a general matter, the FDA's regulations do specifically indicate when manufacturers must provide warnings about fluoride in bottled water. Id. § 165.110(c). If the level of fluoride surpasses the specified maximum concentration, the bottled water is deemed "substandard." Id. § 165.110(c); see also id. § 130.14(a). The label must then state "Contains Excessive Fluoride" or "Contains Excessive Chemical Substances." Id. § 165.110(c)(3).

In establishing the standard of identity for bottled water in 1995, the FDA actually addressed several issues involved in

fluoride consumption, including the notion of a warning requirement regarding dental fluorosis. 60 Fed. Reg. at 57,079-80. The FDA recognized that "an advisory statement . . . may be appropriate to prevent unwanted aesthetic effects from excessive doses of fluoride," and it even "encourage[d] manufacturers to provide such information to consumers, especially on products labeled for infant use." Id. at 57,080. Nevertheless, the FDA declined to mandate a warning in the standard of identity about the risks of dental fluorosis. In fact, the FDA had set acceptable fluoride levels for bottled water -- which were consistent with levels established by the Environmental Protection Agency and the Surgeon General -- and it had required substandard bottled water to indicate excessive fluoride content on the label. Id.; see 21 C.F.R. §§ 165.110(b)(4)(ii), (c). The agency accordingly found "no basis" to follow one comment's suggestion "to require an advisory statement concerning infant fluoride consumption on bottled waters containing 0.3 [parts per million ('ppm')] or more fluoride." 60 Fed. Reg. at 57,080. Such water, after all, would not be substandard. The FDA's fluoride limits for domestic bottled water range from 0.8 to 1.7 ppm when fluoride has been added, and from 1.4 to 2.4 ppm when only naturally occurring fluoride is present. 21 C.F.R. § 165.110(b)(4)(ii)(A), (C). In effect, the proposal rejected by the FDA would have reduced the threshold for a fluoride-related

warning dramatically, from between 0.8 and 2.4 ppm to just 0.3 ppm.[3]

D.

The preemption structure under the NLEA is highly "complex," POM Wonderful, 134 S. Ct. at 2238, but it also forms the framework for evaluating Nemphos's claims. Reduced to its essence, the FDCA and NLEA convey significant powers to the FDA to regulate food safety. This statutory charge reflects the all-around benefits of uniform food labeling. One of the FDA's crucial tools in its regulatory effort is the standard of identity. 21 U.S.C. § 341. The express preemptive force of § 343-1 allows federal regulations such as a food's standard of identity to prevail over certain nonidentical state requirements. Id. § 343-1(a); NLEA § 6(c)(1), 104 Stat. at 2364. The FDA regulates bottled water as a food and has promulgated a standard of identity for it. 21 C.F.R. § 165.110. The parties do not dispute the FDA's capacity to regulate bottled water in this way -- they disagree whether Nemphos's state-law claims about fluoridated bottled water are preempted.

[3] Milligrams per liter, used in the FDA's bottled water regulations, is a roughly equivalent measure to parts per million. See, e.g., 5 Principles and Practices of Water Supply Operations: Basic Science Concepts and Applications 103 (4th ed. 2010).

To summarize further, fluoride has been the subject of a great deal of discussion and regulation by the FDA. The agency has set a range of permissible fluoride levels for bottled water. Id. §§ 165.110(a)(1), 165.110(b)(4)(ii). Manufacturers may optionally add fluoride to bottled water so long as the concentration does not exceed the levels stipulated by the FDA. Id. § 165.110(a)(1). If those regulatory ceilings are breached, the manufacturer must place a warning on the label stating "Contains Excessive Fluoride" or "Contains Excessive Chemical Substances." Id. § 165.110(c)(3). But the FDA requires no particular warning regarding dental fluorosis. 60 Fed. Reg. at 57,080.

Finally, Nemphos does not allege that appellees' bottled water products contained fluoride concentrations above the thresholds set by the FDA. She contends instead that federal statutes and regulations do not preempt her state-law claims.

III.

A.

As part of her claims about Nestlé's and Dannon's bottled water, Nemphos maintains that the manufacturers failed to warn consumers about the risks of dental fluorosis. But for a food such as bottled water that is "the subject of a standard of identity," the NLEA preempts any state "requirement" that is

"not identical to" the federal standard. 21 U.S.C. § 343-1(a)(1).

The term "requirement" in the NLEA's preemption provisions must be read broadly. It includes statutes, regulations, standards, and other obligations arising from state law. See 21 C.F.R. § 100.1(b)(5). In comparable contexts, the Supreme Court has repeatedly instructed that state "requirements" encompass not only positive enactments from the legislature or the executive, but also common-law rules and duties from the judiciary. See Riegel v. Medtronic, Inc., 552 U.S. 312, 324 (2008) ("Absent other indication, reference to a State's 'requirements' includes its common-law duties."); Bates v. Dow Agrosciences LLC, 544 U.S. 431, 443 (2005); Cipollone v. Liggett Grp., Inc., 505 U.S. 504, 521 (1992). There is no indication here that § 343-1(a) distinguishes among different types of state obligations. Nor does the preemption provision in subsection (a)(1) fence off certain foods or certain aspects of the standard of identity -- with the one exception of maple syrup. 21 U.S.C. § 343-1(a)(1). To the extent that Nemphos requests damages rather than explicitly demanding a warning requirement, the analysis remains the same.[4] However Nemphos

[4] Assuming arguendo that the district court correctly concluded that the only even potentially meritorious state-law claims were Nemphos's strict liability and negligence claims, (Continued)

frames her failure-to-warn claim, granting her relief would impose a "requirement" in the form of a warning under Maryland law.

Moreover, Nemphos's proposed "requirement" would not be "identical" to the FDA's standard of identity. Id. The statutory phrase "not identical to," according to the FDA's definition, "means that the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food, or concerning a food container," that either "[a]re not imposed by or contained in," or "[d]iffer from," the applicable federal regulations. 21 C.F.R. § 100.1(c)(4)(i)-(ii). Nonidentical state requirements, whatever their legal provenance, are preempted. In each of the areas selected for preemption, such as the standard of identity in subsection (a)(1), the NLEA sought to ensure a nationally uniform regulatory system, rather than a fifty-state patchwork.

Federal law already covers the ground that Nemphos aims to unsettle through her claims. She seeks a required warning that is additional to and certainly "not identical to" the federal

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see supra note 1, the case law is equally clear. The Supreme Court has specifically found that common-law causes of action for strict liability and negligence constitute state "requirements" subject to preemption. See Riegel, 552 U.S. at 323-24. Assigning liability and awarding damages, after all, may be "a potent method of governing conduct and controlling policy." Id. at 324 (internal quotation marks omitted).

standard. The FDA's standard of identity reaches warnings, and it does not demand a warning about dental fluorosis. The standard of identity for bottled water stipulates, for example, that bottled water intended for infants that is not commercially sterile must bear this conspicuous statement on the label: "Not sterile. Use as directed by physician or by labeling directions for use of infant formula." 21 C.F.R. § 165.110(a)(3)(iii). Yet when fluoride is present within accepted levels, the standard of identity demands merely that the label list fluoride among the ingredients. Id. § 165.110(a)(1), (4); see id. § 165.110(b)(4)(ii). If the bottled water contains fluoride in concentrations beyond those permissible levels, only then must the label bear the warning "Contains Excessive Fluoride" or "Contains Excessive Chemical Substances." Id. § 165.110(c)(3). The parties do not dispute, however, that the fluoride levels in Nestlé's and Dannon's bottled water satisfied federal limits.

The presence of an express preemption clause "does not immediately end the inquiry because the question of the substance and scope of Congress' displacement of state law still remains." Altria Grp., Inc. v. Good, 555 U.S. 70, 76 (2008). But Nemphos's claims do not fall into a gray area. The warning requirement Nemphos seeks is simply not identical to the FDA's

existing standard of identity. As such, her failure-to-warn claim is preempted.[5]

B.

In the other part of her bottled water claims, Nemphos asserts that Nestlé and Dannon misleadingly marketed and advertised their fluoridated bottled water products as especially beneficial to children. But this misleading-marketing claim is essentially the same as her failure-to-warn claim -- albeit dressed in different clothing. The NLEA preempts any state "requirement" that is "not identical to" the federal standard of identity for a food such as bottled water. 21 U.S.C. § 343-1(a)(1). The preemption provision encompasses the labels affixed to a bottle as well as the contents inside. It makes no exception for marketing or advertising in areas regulated by the FDA. The misleading-marketing claim thus fails for the same reason as the failure-to-warn claim. It would impose a

[5] As noted, the NLEA also contains an exception to preemption for "safety" warnings. NLEA § 6(c)(2), 104 Stat. at 2364. This subsection instructs that the statute's preemption provisions "shall not be construed to apply to any requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food." Id. While the NLEA thus expressly preserves an important role for the states when it comes to safety warnings, Nemphos has failed to press arguments relevant to the "safety exception" and appears to have conceded its inapplicability. See Appellant's Reply Br. at 27-28; Oral Arg. at 1:49. As such, we see no need to address the matter here.

requirement under state law that diverges from the federal standard. As such, it would oblige Nestlé and Dannon to issue warnings about the risks of dental fluorosis for their products in the state of Maryland, even though the FDA resolved not to take that same step.

Nemphos's restrictive conception of the standard of identity simply fails to square with the statutory and regulatory structure. A standard of identity does center on the characteristics of the regulated food. See supra Section II.C. The standard of identity for bottled water thus prescribes accepted fluoride levels for the bottle's contents. 21 C.F.R. § 165.110(a)(1); see id. § 165.110(b)(4)(ii). But the statutory reach extends to labeling as well. See supra Section II.C. In particular, it regulates labeling that appears outside the bottle. The standard of identity for bottled water, for example, governs label statements about mineral content, sourcing from a community water system, and sterility. 21 C.F.R. § 165.110(a)(3)(i)-(iii). It further requires the label to announce each of the ingredients contained in the bottled water if any ingredient, such as fluoride, has been added. Id. § 165.110(a)(4); see id. § 101.4(a)(1). The FDA also demands an array of other label statements for bottled water of substandard microbiological, physical, chemical, or radiological quality --

including the "Contains Excessive Fluoride" or "Contains Excessive Chemical Substances" warning. Id. § 165.110(c)(1)-(4).

Beyond the standard of identity in particular, the pattern in the broader statutory and regulatory structure makes this point clear. The four other NLEA preemption provisions specifically involve food labeling, 21 U.S.C. § 343-1(a)(2)-(5), and all five are inscribed under the heading "National uniform nutrition labeling," id. § 343-1. The FDA's own regulations confirm this assessment: the preemption provisions cover state-law requirements "concerning the composition or labeling of food" that are not identical to applicable federal regulations. 21 C.F.R. § 100.1(c)(4). Food composition and food labeling are handled in tandem.

Given that the standard of identity embraces labeling, Nemphos would need to identify an exception to subsection (a)(1) for marketing or advertising. After all, "[e]very labeling is in a sense an advertisement." Kordel v. United States, 335 U.S. 345, 351 (1948). But there is no such exception. By statute, the term "labeling" in this context carries a distinct meaning: it includes "all labels and other written, printed, or graphic matter," whether "upon any article or any of its containers or wrappers" or "accompanying such article." 21 U.S.C. § 321(m)(1)-(2).

The labeling requirements in the FDA's standard of identity for bottled water already address fluoride content. As noted earlier, the FDA found "no basis" for a mandatory warning about dental fluorosis and instead left that option to the manufacturers. 60 Fed. Reg. at 57,079-80. Carving out a preemption exception to subsection (a)(1) for marketing or advertising, when the FDA has already made an explicit determination about fluoride-related labeling, would be not only inconsistent but also potentially confusing. The FDA's standard of identity regulates what manufacturers must say about fluoride content on labels or other visual materials on, around, or accompanying bottled water. 21 C.F.R. § 165.110(a), (c); see 21 U.S.C. § 321(m). Those are, needless to say, prime areas for marketing and advertising. To allow a nonidentical state requirement to contravene the FDA's approach in this area would undermine the NLEA's preemption framework. Without this system of preemption, a manufacturer might be whipsawed by federal regulations delineating permissible labeling and state-law claims of impermissibility. In the five areas designated by the NLEA, preemption shields manufacturers from that predicament. 21 U.S.C. § 343-1(a)(1)-(5). For the foregoing reasons, Nemphos's misleading-marketing claim is preempted.

In reaching this conclusion, we do not suggest that § 343-1(a)(1) preempts all nonidentical marketing and advertising

requirements, even where those requirements are wholly unrelated to packaging and labeling. For example, a state-law requirement that bottled water manufacturers provide warnings regarding dental fluorosis in other media of advertising presents a different question from the one before us today. Because Nemphos limits her marketing and advertising allegations to claims made on labeling and packaging, we need not reach the question of whether state-law requirements for out-of-store advertising and promotions would be preempted. Those matters are not before us, and we express no opinion on them.

IV.

Nemphos also requests relief based on Nestlé's and Gerber's labeling of their respective infant formula and baby food products, which did not provide a warning about the risks of dental fluorosis. Nemphos has now filed three versions of her complaint. Even her latest amended complaint, however, still falls short of stating a plausible failure-to-warn or misleading-marketing claim under federal pleading standards.

Federal Rule of Civil Procedure 8(a)(2) requires that a complaint contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). As the Supreme Court has explained in the context of motions to dismiss, "the pleading standard Rule 8 announces does

not require 'detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007)).

Unlike with her bottled water claims, Nemphos does not allege that the appellee manufacturers added fluoride to the infant formula or baby food products consumed by her daughter. Nor does she allege that Nestlé or Gerber violated federal regulations. Food additives generally are presumed unsafe until approved by the FDA, and the agency regulates the conditions under which approved additives may be used safely. 21 U.S.C. §§ 321(s), 348(a). The FDA in fact forbids the addition of fluoride to any foods other than bottled water, unless the addition results from using fluoridated public water supplies. 21 C.F.R. § 170.45. Although manufacturers may not add fluoride to infant formula or baby food, some fluoride may nevertheless be present in the final product because of municipal water used in the manufacturing process. Nemphos's concern thus involves the failure to warn that fluoride -- even at permissible levels, without any addition by manufacturers -- may contribute to causing dental fluorosis over time.

To impose on manufacturers a duty to warn under these circumstances, Maryland law would oblige Nemphos to allege a good deal more than she has put forward in this action. The

complaint is studded with highly general and conclusory statements that could be adapted to many different products at many different times. It says little about the contents of the infant formula and baby food products in particular, except merely that they contain some amount of fluoride. We are left essentially with a "naked assertion" of liability that lacks the "further factual enhancement" demanded by Rule 8(a)(2). Twombly, 550 U.S. at 557. Even at this stage of the proceedings, something more is required regarding the precise nature of the state-law duty the manufacturers are alleged to have breached, as well as the grounding in state law for whatever warning Nemphos proposes to impose. The vagueness of the allegations simply fails to satisfy the basic "plausibility" requirements of Rule 8 and Twombly, and it provides an inadequate basis for overturning the trial court's dismissal of the infant formula and baby food claims.

"Local Rule 103.6 of the District of Maryland requires that a party requesting leave to amend provide a copy of the proposed amendment to the court." Francis v. Giacomelli, 588 F.3d 186, 197 (4th Cir. 2009). Nemphos, like the plaintiffs in Francis, did not file a separate motion requesting leave to amend her complaint or attach a proposed amended complaint to her opposition brief. We are therefore compelled to find that the district court did not abuse its discretion in dismissing

Nemphos’s third amended complaint with prejudice and denying her a fourth bite at the apple.

V.

For the foregoing reasons, the judgment is affirmed.

AFFIRMED